

Application No. 10/786,186  
Amendment "A" dated March 14, 2006  
Reply to Office Action of December 23, 2005

REMARKS

Applicants and Applicants' attorneys express appreciation to the Examiner and the Examiner's supervisor for the courtesies extended during the recent interview held on March 8, 2006. Reconsideration and allowance of the above-identified application are respectfully requested in view of the foregoing amendments and the following remarks.

Claims 1-17, 20 and 25-28 are pending, wherein claims 1, 8, 14, and 20 have been amended, claims 18, 19 and 21-24 were cancelled, and new claims 25-28 were added.

By the paper, Applications confirm the oral election of claims 1-21 of Group I without traverse. Accordingly, Applicants have cancelled claims 22-24 but reserve the right to pursue these claims in a later-filed divisional application.

As discussed during the Examiner Interview, the disclosed suture separation devices are configured to be attached to a tensioning device for use in joint repair surgery. In joint repair surgery, one or more soft tissue grafts are fixed in a bone tunnel. Sutures are attached to one or more loose ends of the graft and then tensioned with the tensioning device. When attached to the tensioning device, the suture separation devices of the present invention separate the tensioned sutures to facilitate the placement of an interference screw into the bone tunnel. In one embodiment, the suture separation devices can uniformly and desirably position the soft tissue graft strands around the perimeter of the bone tunnel, which can improve the healing and integration of the graft into the bone.

Jain (US 5,207,703) discloses a suture organizer for preventing sutures from becoming entangled during an operation. As taught in Jain, the suture organizer "comprises a flat, platelike member 24 having a rank of fingerlike projections 28 extending from an upper surface 27 thereof." Abstract. The suture separation device in Jain is placed near the patient (e.g., the patient's bedside), and sutures extending from the patient are draped over the organizer to prevent them from becoming entangled, which helps keep the sutures organized until they are tied off. See Figure 1; Abstract. The suture separator described in Jain does not have structure that would allow the suture separator to be attached and/or used with a tensioning device. Nor does the device in Jain have structure that would both separate tensioned sutures and allow placement of an interference screw in a bone tunnel.

Claim 1 as amended recites a suture separation and organization device comprising body means, means for removably attaching the body means to a graft tensioning device; means for separating and organizing a plurality of tensioned suture strands; and a passageway or recess

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through which an interference screw can be inserted during joint repair surgery. The means for separating and organizing the suture strands is positioned on a proximal side of the body (e.g., items 334 and 336 in Figure 7A and items 410 of Figure 9B), and the passageway or recess is positioned either on the distal side of the body (e.g., item 340 of Figure 7A) or between the proximal and distal sides of the body (e.g., item 414 of Figure 9B). In this way the passageway or recess is distally offset relative to said means for separating and organizing a plurality of suture strands. Because of the means for separating and organizing the suture strands are therefore laterally (i.e., proximally) offset relative to the passageway or recess through which an interference screw can be inserted, the suture separation and organization device of claim 1 facilitates insertion of an interference screw into a bone tunnel free from interference from tensioned suture strands exiting the bone tunnel.

Jain neither teaches nor suggests a suture separation and organization device having the combination of elements recited in claim 1 as amended. Because the alleged passageway or recess in the Jain device through which an interference screw can be inserted is on the same side of the device as the posts used to organize sutures, the Jain device lacks the specific structural relationship of elements recited in claim 1 as amended. Because of this, the Jain device likewise lacks the ability to perform the function of the device recited in claim 1 as amended. Claim 1 is therefore believed to be novel and unobvious over Jain.

Claim 14 as amended alternatively claims a suture separation and organization device comprising a body having a proximal side and a distal side; a plurality of attachment passages or recesses in the proximal side of the body for receiving therein a corresponding post of a graft tensioning device; a plurality of spaced-apart suture retention recesses or protrusions disposed on the distal side of said body; and a passageway or recess in the proximal side of said body through which an interference screw can be inserted during joint repair surgery (See Figure 7A of the present Application). Again, all structures alleged to correspond to the attachment passages, the suture retention recesses or protrusion, and the passageway or recess through which an interference screw can be inserted are all located on the same side of the Jain device. Thus, the Jain device lacks the specific structural relationship of elements recited in claim 14 as amended. Because of this, the Jain device likewise lacks the ability to perform the function of the device recited in claim 14 as amended. Claim 14 is therefore believed to be novel and unobvious over Jain.

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New claim 25 alternatively claims the embodiments shown in Figures 9A-10, namely a suture separation and organization device comprising a body having a proximal side and a distal side; a first pair of suture retention recesses or protrusions disposed on a proximal side of the body; a second pair of suture retention recesses or protrusions disposed on a distal side of the body; and a passageway or recess, positioned between said proximal and distal sides of the body, through which an interference screw can be inserted. As discussed during the Examiner interview, this embodiment separates tensioned suture strands both above and below the bone tunnel, facilitating insertion of an interference screw between the tensioned suture strands and into the bone tunnel. In addition, this embodiment better orients the soft tissue graft strands around the perimeter of the bone tunnel, which is believed to promote better healing and attachment of the graft strands over time. The Jain device lacks the specific structural relationship of elements recited in new claim 25. Because of this, the Jain device likewise lacks the ability to perform the function of the device recited in new claim 25. Claim 25 is therefore believed to be novel and unobvious over Jain.

One of skill in the art would not have been motivated to combine the teachings of Jain with Filhol (US 4,692,116), which discloses a dental pin. The devices of Jain and Filhol are non-analogous to each other and cannot be combined without destroying the intended functionality of each. For example, for the device of Jain to function properly, it must be at least approximately 6-12 inches long as shown in the drawings. The dental pin of Filhol, on the other hand, must be tiny enough to be inserted into a tooth. It is never obvious to modify a reference in a manner that renders it unsuitable for its intended purpose. MPEP § 2143.01(V). The same analysis is true for any alleged combination of Jain and Venturini et al. (US 6,749,611), which discloses a bone screw.

Various claims were provisionally rejected under non-statutory double patenting relative to the claims of copending U.S. application Serial No. 10/651,671. In view of the specific amendments added to the claims in the present Application, as well as the completely different amendments added to the claims of the '671 application, Applicants submit that the claims of the two applications have diverged sufficiently such that the claims of the present application are not obvious variations of the claims of the '671 application. Moreover, because this rejection is provisional, Applicants are not required to file a Terminal Disclaimer to respond to this rejection except upon the allowance of the '671 application, and only if the claims of the two applications are at that time found to comprise obvious variants.

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In the event that the Examiner finds remaining impediment to a prompt allowance of this application that may be clarified through a telephone interview, the Examiner is requested to contact the undersigned attorney.

Dated this 14<sup>th</sup> day of March 2006.

Respectfully submitted,



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